



# ***Biosecurity: Balancing Risk and Research at Biomedical and Bioscience Laboratories***

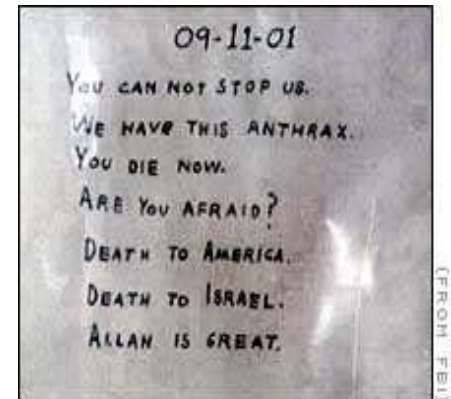
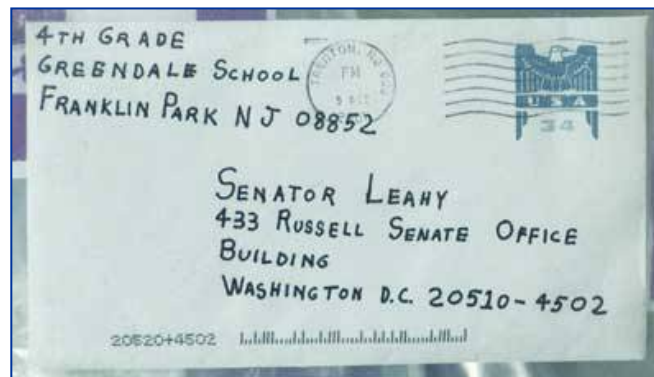
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# Bioterrorist and Biological Weapons Threat

- Increase in awareness of bioterrorist and biological weapons threat
- Emerging US security regime: policies with two sets of objectives
  - Enhance ability to respond to public and agricultural health emergencies
  - Reduce the risk that the powers of bioscience and biotechnology could be used maliciously
- Focus of this talk is biosecurity: protection of certain biological materials at bioscience facilities from theft and sabotage



# Problem: Bioscience Research and International Security

- Recent realization that bioscience facilities are potential sources of viable and virulent pathogens and toxins
  - Bioscience community not accustomed to security
- New US regulatory environment has broad international repercussions
  - International community must address this issue
- Control of certain biological materials is necessary
  - But *how* that is achieved must be carefully considered and implemented



# New US Regulatory Environment for Biosecurity

- **USA PATRIOT Act of 2001 – US Public Law 107-55**
  - **Restricted Persons**
- **Bioterrorism Preparedness Act of 2002 – US Public Law 107-188**
  - **42 CFR 73 (Human)**
  - **9 CFR 121 (Animal)**
  - **7 CFR 331 (Plant)**
- **If a facility has one or more of 82 “Select Agents,” then it is subject to the regulations**



# Scientific Concerns

- Top-down security regime
- No need to acquire biological material from a bioscience facility to pursue bioterrorism
- Nature of the material makes diversion extremely difficult to prevent
- Dual-use characteristics of biological materials and technology make identification of illegitimate activities extremely difficult



## REPORTS

### Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

Jeronimo Cello, Aniko V. Paul, Eckard Wimmer\*

9 AUGUST 2002 VOL 297 SCIENCE [www.sciencemag.org](http://www.sciencemag.org)

*Journal of Virology*, Feb. 2001, p. 1205-1210  
0022-538X/01/504-00+0 DOI: 10.1128/JVI.75.3.1205-1210.2001  
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Vol. 75, No. 3

### Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

RONALD J. JACKSON,<sup>1,2\*</sup> ALSTAIR J. RAMSAY,<sup>2,3</sup> CARENA D. CHRISTENSEN,<sup>3</sup> SANDRA BEATON,<sup>3</sup> DIANA F. HALL,<sup>1,2</sup> and IAN A. RAMSHAW<sup>1</sup>

*Post Animal Control Cooperative Research Centre, CSIRO Sustainable Ecosystems,<sup>1</sup> and Division of Immunology and Cell Biology, John Curtin School of Medical Research, Australian National University,<sup>2</sup> Canberra, Australia*



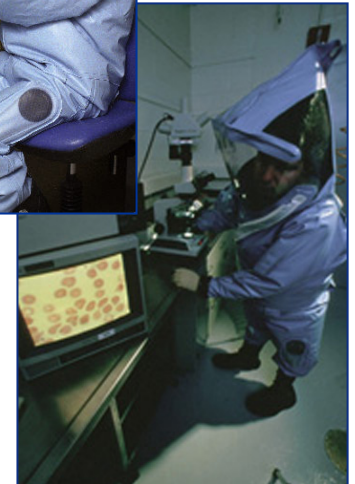
# Security Concerns

- The most likely threat to viable and virulent biological material is from someone who has legitimate access to the facility
  - Traditional facility security approaches focus on protecting against outside adversaries
- Very few agents can be easily and successfully deployed as mass-casualty weapons
  - US regulations based on 82 agents and toxins of various degrees of attractiveness to adversaries
- No protection if personnel do not understand and accept security
  - Evasion of security measures
  - Destruction of collections and withdrawal from research on Select Agents



# Need for Biosecurity

- Known collections of viable and virulent agents may be attractive to certain types of adversaries
- Designing appropriate mechanisms for biosecurity depends on an understanding of biological materials and research
- Achieving biosecurity depends on the involvement and cooperation of the scientific community
- Most important biosecurity measures should support and complement existing biosafety measures
- Need for a comprehensive approach and widely accepted model for biosecurity



# International Opportunity to Achieve a Balance

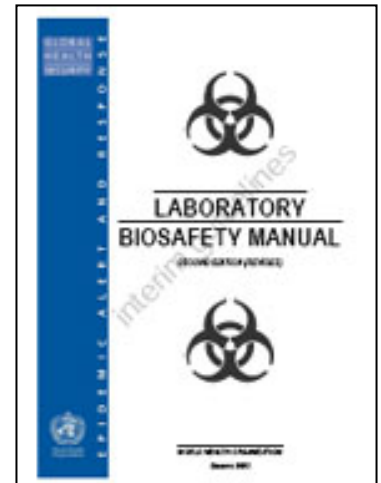
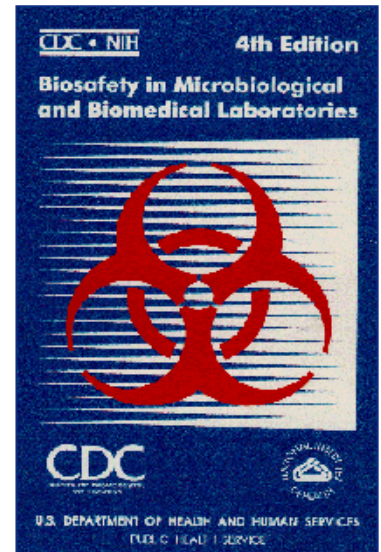
- International community can develop intellectually defensible and widely achievable biosecurity guidelines
- Employ a risk management approach
  - Risk will always exist: every asset cannot be protected against every threat
  - Distinguish between “acceptable” and “unacceptable” risks
- Conduct an agent-based security risk assessment
  - Risk = (Threat Potential) (Consequences)
  - Ensure that protection for an asset, and the cost, is proportional to the risk of theft or sabotage of that asset





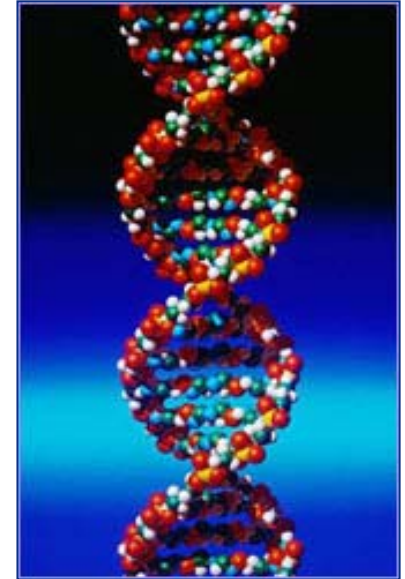
# Biosafety as a Model

- **Biosafety aims to reduce or eliminate accidental exposure to or release of hazardous agents**
  - CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories” (BMBL)
  - WHO “Laboratory Biosafety Manual” (LBM)
- **Four biosafety levels**
  - Graded application of practices and techniques, laboratory equipment, and facility design (“containment”)
  - Based on agent safety risk assessments
- **Biosafety now considered standard microbiological practice around the world**



# Summary

- **Necessary to take steps to reduce the likelihood that certain pathogens and toxins could be stolen from bioscience facilities**
- **Critical that these steps are designed specifically for biological materials and research**
- **Most biosecurity measures should reinforce and complement existing biosafety measures**
- **Need to involve scientific community in development to build understanding and acceptance**





## Contact Information

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